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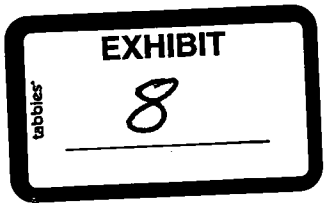
UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

COORDINATION PROCEEDING	§	DOCKET No. _____
SPECIAL TITLE [Rule 1550(b)]	§	**MDL 1657**
IN RE VIOXX CASES	§	**SECTION L**
	§	JUDGE FALLON
	§	MAG. JUDGE KNOWLES
	§	**COMPLAINT**
KAREN A. MONTALTO, SONYA M. MONTGOMERY, BETTY S. MOODY, JUNE G. MOORE, TAJUANA BAKER, Individually and As Representative of the Estate of GAIL MOORE, JODIE L. MOORE, PERCEINA MOORE, ROSEMARY MORAN, CLIFFORD S. MORGAN, BARBARA R. MORROW, DEBORAH MORGAN, Individually and As Representative of the Estate of WILLIAM MORTON, JOHNNIE MARIE MOSS, IRENE MOSTEK,	§	1. Strict Products Liability 2. Negligence 3. Misrepresentation and Fraud 4. Breach of the Implied Warranty of Merchantability 5. Breach of Implied Warranty of Fitness for a Particular Purpose 6. Breach of Expressed Warranty 7. Gross Negligence/Malice



DONALD B. MOWBRAY, §
ESPERANZA A. MULERO, §
DORENDA K. MURRELL, §
MARY F. MURRELL, §
MATTIE MYERS, §
PHILIP E. NALLY, §
JULIA NEELY, §
ANNA M. NELSON, §
TIMOTHY J. NEWCOMB §
JOHN L. NEWMAN §
TERRY M. NEWSOM, §
EMMA J. NEWSOME, §
DOROTHY P. NEWTON, §
MICHAEL LAUTNER, Individually and §
As Representative of the Estate of §
MARILYN J. NICELY, §
EVELYN B. NICHOLS, §
BESSIE M. NICHOLSON, §
GARRY L. NICKERSON, §
JAMES S. NIX §
ANNA L. NOLAN, §
GAIL A. NORDEMAN, §
PATRICIA L. NORDSTROM, §
JANET N. OSBORNE, Individually and §
As Representative of the Estate of §
ETHEL I NORRIS, §
MARGIE A. NORSEWORTHY, §
JAMES E. NOWELL, §
MARCELINA G. OCHOA, §
VICTORIA M. O'DONNELL, §
REBECCA L. OLSEN §
MARY A. O'NEAL, §
CARLA J. OWENBY, §
BRUCE D. OWENS, §
JOHNNY OWENS, §
DAWN M. JACKSON-PAGE, Individually and §
As Representative of the Estate of §
DAVID J. PAGE, §
MARTHA P. PAGE, §
PATRICK PAIGE, Individually and §
As Representative of the Estate of §
RACHEL L. PAIGE, §

DEBRA S. HARNESS, Individually and §
As Representative of the Estate of §
ADOLA G. PALERMO, §
BRENDA PARGO, Individually and §
As Representative of the Estate of §
RICHARD J. PARGO, §
MARVIN PARKER, §
ROSYLAN M. PARKER, Individually and §
As Representative of the Estate of §
EDITH E. PARKER, §
RONALD L. PASE, §
CAROL A. PATRICK, §
JOHN P. PATTI, §
MARVIN R. PATTON, §
PHILLIP W. PAYNE, §
PATRICK K. PEALO, §
CONRADO N. PENA, §
LOUIS PENLEY, §
BARBARA PEREZ, §
L.C. PERRY, §
BOBBIE J. PERRY, §
MARY E. PETTY, §
L.J. PETTYJOHN, §
NORMA L. PICKETT, §
MARY PIERCE, §
BARBARA E. PIETSCH, §
CRAIG A. PINGLE, §
LOIS A. PINKSTON, §
BETTY J. PITTS, §
RICHARD A. PIVONKA, §
ELIZABETH POPP, §
CAROL POSPISIL, §
RAYMOND D. POSTON, §
LAQUITA R. LOWERY, Individually and §
As Representative of the Estate of §
BETTYE R. POWELL, §
RUTHIE M. PRESCOTT, §
DALE E. PRITCHARD, §
RONALD L. PRUDHOMME, §
RAMON QUINONES, §
FREDRICK D. RARDIN, §
CHARLOTTE MILAN, Individually and §

As Representative of the Estate of	§
BESSIE LEE JACKS RATCLIFF,	§
MARTHA G. RAY,	§
CHARLES RAYBURN,	§
DIANE READ,	§
KATHY E. REDWINE,	§
BETTY J. REED,	§
WILLIAM R. REESE,	§
LESLIE M. REINSTADTLER,	§
JAMES T. REYNOLDS,	§
DAVID REYNOLDS, Individually and	§
As Representative of the Estate of	§
ELEANOR H. REYNOLDS,	§
VIOLA REYNOLDS,	§
ROBERT RICHARDS, Individually and	§
As Representative of the Estate of	§
RUTH K. RICHARDS,	§
ANITRA RICHARDSON, Individually and	§
As Representative of the Estate of	§
THOMAS R. RICHARDSON,	§
CHRISTINE L. RICHARDSON,	§
CALVIN J. RICHISON,	§
RUTH E. RICHMOND,	§
JEFFERY D. RIFE,	§
NARVIE L. RILEY,	§
JAMES RILEY, Individually and	§
As Representative of the Estate of	§
LINDA S. RILEY,	§
KATHLEEN A. RINKER,	§
SAMUEL B. RITROVATO,	§
HECTOR M. RIVERA CRUZ,	§
BRITTANY M. ROBERTSON,	§
CELESTE B. ROBERTSON,	§
CATHY SHRADER, Individually and	§
As Representative of the Estate of	§
TAMMY S. ROBERTSON,	§
PHYLLIS ROBINSON-HARTNESS,	§
BOBBIE G. ROBINSON,	§
HARVEY L. ROBINSON.	§

V.

MERCK & CO.,INC. §

ORIGINAL COMPLAINT

COMES NOW each of the above named Plaintiffs and makes the following allegations against Defendant MERCK & CO., INC.:

JURISDICTION AND VENUE

1.1 The jurisdiction of this Court over the subject matter of this action is predicated on diversity jurisdiction pursuant to 28 USC Section 1332. The amount in controversy exceeds $75,000, exclusive of interest and costs.

1.2 Venue is proper for each Plaintiff in the District where a substantial part of the events or omissions giving rise to each Plaintiff's claims occurred, i.e., where that Plaintiff or that Plaintiff's Decedent was prescribed, purchased, and/or consumed Vioxx and/or the injuries giving rise to that Plaintiff's claims occurred, as alleged later herein. The claims are being filed in this District pursuant to MDL No. 1657 Pretrial Order No. 11. No Plaintiff named herein waives transfer for trial to the District of proper venue for his or her claims.

PARTIES

2.1 Plaintiffs are as follows:

1. Karen A. Montalto of OH.
2. Sonya M. Montgomery of GA.
3. Betty Moody of OH.
4. June Moore of SC.
5. Jodie Moore of IL.
6. Perceina Moore of VA.
7. Rosemary Moran of MS.
8. Clifford S. Morgan of OH.
9. Barbara R. Morrow of NC.

10. Johnnie Marie Moss of MS.
11. Irene Mostek of WI.
12. Donald Mowbray of VA.
13. Esperanza Mulero of MI.
14. Dorenda K. Murrell of FL.
15. Mary F. Murrell of MS.
16. Mattie Myers of MS.
17. Philip E. Nally of CA.
18. Julia Neely of MS.
19. Anna Nelson of OH.
20. Timothy Newcomb of OH.
21. John L. Newman of FL.
22. Terry M. Newsom of TN.
23. Emma Newsome of FL.
24. Dorothy Newton of AL.
25. Evelyn Nichols of OK.
26. Bessie M. Nicholson of NC.
27. Garry Nickerson of MI.
28. James Nix of OR.
29. Anna L. Nolan of LA.
30. Gail Nordeman of OH.
31. Patricia L. Nordstrom of FL.
32. Margie A. Norseworthy of OK.
33. James E. Nowell of VA.
34. Marcelina G. Ochoa of ID.
35. Victoria M. O'Donnell of MT.
36. Rebecca L. Olsen of WI.
37. Mary A. O'Neal of NC.
38. Carla J. Owenby of OK.
39. Bruce D. Owens of AZ.
40. Johnny Owens of GA.
41. Martha P. Page of GA.
42. Marvin Parker of SC.
43. Ronald L. Pase of AZ.
44. Carol A. Patrick of WV.
45. John P. Patti of MI.
46. Marvin R. Patton of OK.
47. Phillip W. Payne of NC.
48. Patrick K. Pealo of NY.
49. Conrado N. Pena of NV.
50. Louis Penley of WV.
51. Barbara Perez of FL.

52. L.C. Perry of MS.
53. Bobbie J. Perry of IN.
54. Mary E. Petty of NY.
55. L. J. Pettyjohn of NC.
56. Norma L. Pickett of OK.
57. Mary Pierce of MS.
58. Barbara E. Pietsch of OH.
59. Craig A. Pingle of OH.
60. Lois A. Pinkston of AZ.
61. Betty J. Pitts of GA.
62. Richard A. Pivonka of AZ.
63. Elizabeth Popp of WI.
64. Carol Pospisil of WV.
65. Raymond D. Poston of MS.
66. Ruthie M. Prescott of VA.
67. Dale E. Pritchard of NC.
68. Ronald L. Prudhomme of TX
69. Ramon Quinones of FL.
70. Fredrick D. Rardin of MI.
71. Martha G. Ray of SC.
72. Charles Rayburn of TN.
73. Diane Read of CO.
74. Kathy E. Redwine of MO.
75. Betty J. Reed of FL.
76. William R. Reese of NC.
77. Leslie M. Reinstadtler of PA.
78. James T. Reynolds of VA.
79. Viola Reynolds of MS.
80. Christine L. Richardson of NV.
81. Calvin J. Richison of CA.
82. Ruth E. Richmond of NC.
83. Jeffery D. Rife of FL.
84. Narvie L. Riley of AL.
85. Kathleen A. Rinker of WI.
86. Samuel B. Ritrovato of FL.
87. Hector M. Rivera Cruz of MA.
88. Brittany M. Robertson of MS.
89. Celeste B. Robertson of OH.
90. Phyllis Robinson-Hartness of NC.
91. Bobbie G. Robinson of NC.
92. Harvey L. Robinson of IA.

2.2 The above Plaintiffs were prescribed, purchased, ingested, and/or was injured by the prescription medication Vioxx in their county of residence on or before September 30, 2004. Each experienced injuries, including heart attack, stroke, pulmonary embolism, arrhythmia, angina, organ failure due to thrombosis, cardiovascular adverse event, and/or vascular incident, after ingesting and caused by Vioxx.

1. Decedent Gail Moore of GA.
2. Decedent William Morton of VA.
3. Decedent Marilyn Nicely of MI.
4. Decedent Ethel I. Norris of OH.
5. Decedent David J. Page of SC.
6. Decedent Rachel L. Paige of MS.
7. Decedent Adola G. Palermo of NE.
8. Decedent Richard J. Pargo of MS.
9. Decedent Edith E. Parker of CA.
10. Decedent Bettye R. Powell of AR.
11. Decedent Bessie Lee Jacks Ratcliff of MS.
12. Decedent Eleanor H. Reynolds of FL.
13. Decedent Ruth K. Richards of PA.
14. Decedent Thomas R. Richardson of OH.
15. Decedent Linda S. Riley of FL.
16. Decedent Tammy S. Robertson of WV.

2.3 Decedents were prescribed, purchased, ingested, and were injured by the prescription medication Vioxx on or before September 30, 2004. Each experienced injuries, including heart attack, stroke, pulmonary embolism, arrhythmia, angina, organ failure due to thrombosis, cardiovascular adverse event, and/or vascular incident, after ingesting Vioxx and ultimately, death, which was caused or contributed to by Vioxx.

2.4 Defendant, Merck & Co., Inc., is a New Jersey corporation with its principal place of business in New Jersey. Plaintiffs intend to sue that group or association doing

business as Merck, who manufactured, promoted, sold and distributed the drug Vioxx to pharmacies and physicians worldwide and in the United States, and specifically this District and in each Plaintiff and/or Decedent's District of residence. Plaintiffs intend to sue the private corporation, individual unincorporated association and/or partnerships doing business under the name of "Merck," which manufactured, sold and was responsible for the marketing of Vioxx in the United States. Plaintiffs reserve the right, if needed, to properly reflect the correct party.

BACKGROUND FACTS

3.1 At all relevant times, Merck was in the business of developing, researching, selling, distributing, designing, manufacturing, testing, evaluating, licensing, labeling and/or marketing, either directly or indirectly through third parties or related entities, pharmaceutical drugs, including Vioxx.

3.2 Vioxx is the brand name of Rofecoxib, one of a class of drugs called prostaglandins, which drugs work to reduce inflammation and pain by providing analgesic and anti-inflammatory benefits to persons with, among other conditions, arthritis and muscle or joint pain. Prostaglandins are COX (cyclooxygenase) inhibitors. COX enzymes metabolize arachidonic acid to produce prostaglandins.

3.3 Vioxx is a COX-2 inhibitor, which is designed to produce prostaglandins at inflammatory sites and to produce prostacyclin, a vasodilator and an inhibitor of platelet aggregation.

3.4 Merck submitted an Application to Market a New Drug for Human Use

("NDA") for Rofecoxib to the United States Food & Drug Administration (hereinafter referred to as the "FDA") on November 23, 1998, for tablets at doses of 12.5 mg. and 25 mg. for relief of the signs and symptoms of osteoarthritis, the management of acute pain, and the treatment of primary dysmenorrhea. This application was denoated NDA 21-042 by the FDA.

3.5 Merck also submitted an NDA for Rofecoxib to the FDA on November 23, 1998, for oral suspension at doses of 12.5 mg./Ml and 25 mg/ml for relief of the signs and symptoms of osteoarthritis, the management of acute pain and the treatment of primary dysmenorrhea. This application was denoted NDA 21-052 by the FDA.

3.6 On or about May 20, 1999, the FDA approved NDA 21-042 and NDA 21-052 for Rofecoxib (Vioxx) for the relief of the signs and symptoms of osteoarthritis, the management of acute pain and the treatment of primary dysmenorrhea. Thereafter, these events set forth below took place.

3.7 On December 16, 1999, the FDA sent Merck an official warning letter complaining that the promotion pieces that promoted Vioxx (Rofecoxib) were false and misleading because they contained misrepresentations of Vioxx's safety profile, unsubstantiated comparative claims and were lacking in fair balance.

3.8 In 2000, researchers began warning about Vioxx's possible cardiovascular risks. According to the Washington Post, which interviewed independent researchers who collected and reviewed the Vioxx data, there was data from a company study that found users had four times as many heart attacks and strokes as those who used another painkiller.

Nevertheless, Merck repeatedly reassured the medical and financial communities that Vioxx was safe.

3.9 In June of 2000, a study (VIGOR) found Vioxx patients had double the rate of serious cardiovascular problems than those on Naproxen, an older non-steroidal anti-inflammatory drug (NSAID). The VIGOR data revealed that (a) patients on Vioxx were five time more likely to suffer a heart attack as compared to patients on Naproxen; and (b) patients on Vioxx were 2.3 times more likely to suffer serious cardiovascular disease (including heart attacks, ischemic stroke, unstable angina, and sudden unexplained death) as compared to patients on Naproxen.

3.10 On March 27, 2000, Merck issued a press release leading off with the finding that Vioxx caused fewer digestive tract problems than Naproxen. Merck continued to assert that it was not that Vioxx caused cardiovascular problems, but that Naproxen protected against them.

3.11 In June 2000, industry-sponsored studies presented to the European United League Against Rheumatism ("EULAR"), an organization of which Merck is a corporate sponsor, showed that Vioxx use resulted in a statistically significant increase in hypertension and myocardial infarction.

3.12 In August 2000, Merck denied the studies presented to EULAR in *Pharmacy Today*, the official publication of the American Pharmaceutical Association.

3.13 From March 2000 through September 2004, Merck continued to represent that it was not that Vioxx caused cardiovascular problems, but that Naproxen protected against

those problems.

3.14 Merck engaged in a massive advertising and sampling program, reportedly employing an additional 700 salespersons to "detail" Vioxx to physicians. The effect was a more than $2 billion profit for Merck in 2000, and a twenty-three percent (23%) market share for Vioxx.

3.15 In November 2000, *The New England Journal of Medicine* published the VIGOR study (VIGOR = Vioxx Gastrointestinal Outcomes Research).

3.16 In February 2001, an FDA Advisory Panel recommended the FDA require a label warning of Vioxx's possible link to cardiovascular problems.

3.17 In documents dated February 8, 2001, according to the FDA Advisory Committee Briefing Document in the VIGOR Study, the potential advantage of decreasing the risk of complicated [gastrointestinal side effects] was paralleled by the increased risk of developing cardiovascular thrombotic events. An FDA memorandum discussing the overall safety of Vioxx related that the VIGOR Study found there were more overall deaths among study participants taking Vioxx than those taking Naproxen (22 and 15, respectively).

3.18 In April 2001, Public Citizen, a well-respected national non-profit public interest organization, advised the public not to use Vioxx because of potential heart-related risks. Despite the results of the VIGOR Study and the warnings from Public Citizen, Merck continued to promote the Vioxx drug in a way that minimized this risk.

3.19 On May 22, 2001, Merck issued a press release through the *PR Newswire* that stated, "In response to news and analyst reports of date the Company first released a year

ago, Merck & Co., Inc. today reconfirmed the favorable cardiovascular safety profile of Vioxx."

3.20 On August 22, 2001, Dr. Eric Topol and Dr. Steven Nessen's article, "Risk of Cardiovascular Events Associates With Selective Cox-2 Inhibitors," was published in the *Journal of the American Medical Association* ("JAMA") and reported the findings of the Cleveland Clinic's study that "current data would suggest that the use of these so-called 'COX-2 inhibitors' might lead to increased cardiovascular events."

3.21 On August 21, 2001, the day before the JAMA article was published, Merck commented in a published report in the *Bloomberg News* that, "We have additional data beyond what they [Topol and Nessen] cite, and the findings are very, very reassuring. Vioxx does not result in any increase in cardiovascular events compared to placebo."

3.22 On August 23, 2001, Merck stated in a press release: "The Company stands behind the overall and cardiovascular safety profile...of Vioxx."

3.23 On September 17, 2001, the FDA warned Merck to stop misleading doctors about Vioxx's effect on the cardiovascular system, ordering Merck to send doctors a letter "to correct false or misleading impressions and information" about Vioxx's effect on the cardiovascular system. The FDA warned Merck that its promotional campaigns for Vioxx were minimizing the cardiovascular risks of the drug and misrepresenting the results of the 2000 study.

> You have engaged in a promotional campaign that minimizes the potentially serious cardiovascular findings that were observed in the Vioxx Gastrointestinal Outcomes Research (VIGOR) study and, thus, misrepresents the safety profile for

> Vioxx. Specifically, your promotional campaign discounts the fact that the VIGOR Study where patients using Vioxx were observed to have a four-to-five fold increase in myocardial infarctions (MIs) compared to patients on the comparator non-steroidal anti-inflammatory drug (NSAID), Naprosyn (Naproxen).

3.24 Merck was also aware at this time of the increased risks of thrombotic (blood clotting) adverse effects, such as strokes and blood clots in the legs, hypertension and altered kidney function. However, Vioxx was, by then, a blockbuster moneymaker ($1.5 billion in 2000 and then $2.5 billion in 2003) and Merck decided to protect its cash cow at all costs.

3.25 On January 12, 2002, Dr. Wayne A. Ray, a Professor of Preventive Medicine at Vanderbilt University and others reported in an article published in *The Lancet* that Naproxen did not have significant protective cardiovascular effect, and that Vioxx, when taken at higher dosages, which had become common, posed an increased risk of heart-related problems.

3.26 In April 2002, the FDA told Merck to add information about cardiovascular risks to the Vioxx label.

3.27 On October 5, 2002, the study done at Vanderbilt University published in *The Lancet* noted: "Patients taking 50 mg. of Vioxx for more than five (5) days demonstrated a seventy percent (70%) greater likelihood of developing coronary heart disease (CHD)."

3.28 In 2002, Merck was spending more than $100 million per year in direct-to-consumer advertising. Such monies were used as direct representations of Merck's claims that Vioxx was safe, clearly underestimating the risks of cardiovascular events.

3.29 In 2002 and 2003, Merck refused the requests from the American Heart

Association, the National Stroke Association, and the Arthritis Foundation that Merck conduct additional safety studies. Merck continued claiming that Vioxx was safe and that the company did not plan to conduct any such study.

3.30 On October 30, 2003, an article published in *The Wall Street Journal* reported that another study sponsored by Merck and presented at the annual meeting of the American College of Rheumatology confirmed an increased risk of heart attacks in patients using Vioxx. According to *The Wall Street Journal,* within the first 30 days of taking Vioxx, the risk of a heart attack was increased thirty percent (30%) as compared to Celebrex. This study looked at the records of 54,475 Medicare patients, all of whom were over 65, and was described by Eric Topol as "the best study to date."

3.31 Through October 2003, almost 2,000 adverse cardiovascular events had been voluntarily reported to the FDA. Those events included myocardial infarctions, cardiac arrests, and cardiac failures. The FDA's Adverse Event Report System ("AERS") is a voluntary system, and an FDA official has estimated in testimony before the FDA Advisory Committee that ninety percent (90%) or more of the adverse events are not reported to the FDA.

3.32 In 2003, Dr. Jerry Avorn, a Divisional Director at Brigham Women's Hospital in Boston, and his colleague, Dr. Daniel H. Solomon, reported on a Merck-financed study based on a survey of patient records that found Vioxx, even at some moderate dosages, increased cardiovascular risks.

3.33 Merck disputed the findings of the Avorn-Solomon Study, and the name of the

company epidemiologist who had worked on the study was removed from the report before it was published in a medical journal.

3.34 In May 2004, the results of a study funded by the Canadian government were published in *The Lancet*. The study culled data from 1.3 million elderly patients (66 and older) who were taking Vioxx, Celebrex, other NSAIDs, and no medication. The records from approximately 130,000 persons randomly culled from the population base found that persons taking Vioxx had an eighty percent (80%) increase in hospital admissions for congestive heart failure within one year of starting therapy when compared to persons taking NSAIDs.

3.35 On August 25, 2004, Dr. David Graham, Associate Director for Science in the FDA's Office of Drug Safety, presented results of a database analysis of 1.4 million patients that concluded that Vioxx users are more likely to suffer heart attack or sudden cardiac death than those taking Celebrex or an older NSAID.

3.36 It has been reported that Dr. Graham and his collaborators had linked Vioxx to more than 27,000 heart attacks or sudden cardiac deaths from the time it came on the market in 1999 through 2003. In fact, the study drew on data from about 1.4 million Kaiser Permanente patients who had taken one of the NSAIDs. That included 40,405 patients who had taken Celebrex and 26,748 who had taken Vioxx. The *projections* of the potential impact came from figuring out a rate of increased risk among the Kaiser patients and then applying that risk to the number of American prescriptions for Vioxx in the years 1999 through 2003. Of the additional 27,785 serious heart problems the study projected for the

entire American population, 12,940 would have come in patients taking high doses of Vioxx and 14,845 with low doses. The actual numbers in the study database were far smaller, i.e., the study estimated that, of 58 cases of heart attacks or sudden cardiac death among patients in the database who were taking the low dose of Vioxx, 21 of them would not have occurred had they all been taking Celebrex instead. For the high dose, it was 9.7 serious heart problems out of 10 that would not have happened.

3.37 Dr. Graham's study found that people taking a high dose of Vioxx were 3.69 times more likely to have a serious cardiac event as people taking Celebrex, while the ratio for people taking the lower dose was 1.5. The study also concluded that there was no evidence of a "substantial benefit with the high dose strength" of Vioxx that would "counter-balance the level of cardiovascular risk" shown in various studies of the drug.

3.38 On August 26, 2004 and thereafter, Merck continued to minimize the health risks of taking Vioxx. Merck stated in a press release: "Merck stands behind the efficicacy, overall safety, and cardiovascular safety of Vioxx."

3.39 In August 2004, Merck complained to the FDA in an email since provided to Senate Finance Committee Chairman, Charles Grassley that the FDA had not lived up to a prior agreement to alert the company before releasing any negative information about Merck's products.

3.40 In 2003 or 2004, Merck began a three-year, 2,600 patient randomized trial to see whether Vioxx could claim that it protects against the recurrence of colon polyps, which can become cancerous. After 18 months of treatment, researchers had observed a higher

heart attack and stroke risk in patients using Vioxx, when Vioxx was compared to a placebo and not to another NSAID. The FDA says that 3.5% of the patients on Vioxx had suffered a heart attack or stroke compared to 1.9% on the placebo.

3.41 On September 14, 2004, Merck delivered to the colon polyp trial's Data and Safety Monitoring Board, an independent panel of specialists hired to catch harmful developments during trial, the heart attack and stroke data for the previous six months.

3.42 From the beginning of the study, the safety monitors noted an increased rate of hypertension among the Vioxx group, and in 2003 and early 2004, they found more people in the Vioxx group were having cardiovascular events than in the placebo group. The numbers were small, in part because people with heart disease had been screened out of the trial.

3.43 Merck claims that on September 23, 2004, it learned that patients taking Vioxx in a study were twice as likely to suffer a heart attack or stroke as those on the placebo. In fact, on September 17, 2004 Dr. James Neaton and three other safety committee members held their regularly scheduled telephone conferences with Merck representatives and the principal investigator for the colon polyp trial.

3.44 The information that Dr. Neaton faxed to the principal investigator from the "unblended" data showed that, within the small population of people suffering from cardiovascular disease, the number from the Vioxx group, after 18 months of study, was twice as high as the placebo group, i.e., 15 heart attacks or strokes per 1,000 patients per year versus 7.5 for the sugar pill.

3.45 On September 30, 2004, Merck withdrew Vioxx from the United States market

and more than 80 other countries in which Vioxx was marketed.

3.46 In October 2004, Dr. Eric Topol, Chief of Cardiovascular Medicine and Chief Academic Officer of the Cleveland clinic, as well as the co-author of the VIGOR Study, estimated Vioxx may have caused between 30,000 to 100,000 heart attacks and strokes, many of which were "preventable" because patients could have been taking other safer drugs.

3.47 Dr. Topol wrote in the October 21, 2004 issue of *The New England Journal of Medicine:*

> Sadly, it is clear to me that Merck's commercial interest in Rofecoxib [Vioxx] sales exceeded its concern about the drug's potential cardiovascular toxicity. Had the company not valued sales over safety, a suitable trial could have been initiated rapidly at a fraction of the cost of Merck's direct-to-consumer advertising campaign.

3.48 The Merck spokesperson made further misrepresentations by stating on September 30, 2004 that the latest study (the colon polyp trial) was the first clinical trial to show such results and that the company took "immediate" action on receiving the data.

3.49 At all times relevant and material hereto, Merck acted and gained knowledge itself and by and through its various agents, servants, employees, and/or ostensible agents.

STRICT PRODUCTS LIABILITY

4.1 Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein and additionally or in the alternative, if same be necessary, allege as follows:

4.2 Merck created, manufactured, designed, tested, labeled, packaged, marketed, sold, advertised, distributed, supplied and/or placed into the stream of commerce the

dangerous drug Vioxx described herein, which Merck distributed throughout the world, including Texas. Under the doctrine of Strict Products Liability, Plaintiffs would show that the drug Vioxx was defectively designed, marketed, and manufactured and was unsafe for its intended purposes at the time the drug left the control of Merck and was sold.

4.3 Each Plaintiff or Decedent was using Vioxx in the manner for which it was intended and/or in a reasonably foreseeable manner. Plaintiffs and Decedents and their prescribing physicians were not aware of and reasonably could not have discovered the dangerous nature of Vioxx.

4.4 The drug Vioxx was unaccompanied by proper warnings regarding the injuries associated with the use of it and the comparative severity and duration of such injuries. The warnings given did not accurately reflect the symptoms, scope, frequency, or severity of such injuries. Additionally, or in the alternative, Merck failed to perform adequate testing in that adequate testing would have shown that Vioxx possessed undisclosed risks of potentially serious injuries. Full and proper warnings accurately and fully reflecting the symptoms, scope, frequency, and severity of the harm should have been made with respect to the use of this drug.

4.5 Merck knew, or should have known, that Vioxx was a dangerously defective drug that posed unacceptable risks of serious injury, which risks were unknown and unknowable by Plaintiffs, Decedents and their prescribing physicians.

4.6 Vioxx was defective due to inadequate warnings or instructions because, after Merck knew or should have known of the risk of serious injury from Vioxx use, it failed to

provide adequate warnings to Plaintiffs, Decedents and/or their physicians, and Merck continued to aggressively promote the dangerously defective product. Merck failed to give warnings (1) that could reasonably be expected to catch the attention of a reasonably prudent person, in the circumstances that the product was used; (2) that were comprehensible to the average user; and (3) that conveyed a fair indication of the nature and extent of the danger. The failure to give these warnings rendered Vioxx dangerous to an extent beyond that which would be contemplated by the ordinary users of the product with ordinary knowledge common to the community.

4.7 The drug Vioxx was defective in design or formulation in that, when it left the hands of the manufacturer and/or distributor, the foreseeable risks far exceeded the benefits associated with the design or formulation. Alternatively, the drug Vioxx was defective in design or formulation, in that, when it left the hands of the manufacturer and/or supplier, it was unreasonably dangerous, it was more dangerous than an ordinary consumer would expect, and it was more dangerous than other drugs of the same class as Vioxx.

4.8 Merck is liable under the theory of Strict Product Liability as set forth in Section 402A of the Restatement of Torts 2d and under Texas Strict Product Liability Law. Merck was at all times material hereto engaged in the business of designing, manufacturing, distributing, marketing, promoting, and placing into the stream of commerce the drug. Merck is in the business of selling Vioxx with the expectation that such product would reach the user without substantial change in the condition in which it was sold. The drug Vioxx reached the ultimate users without substantial change in the condition in which it was sold.

NEGLIGENCE

5.1 Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein and additionally or in the alternative, if same be necessary, allege as follows:

5.2 Merck was negligent in designing, manufacturing, marketing, promoting, distributing and placing into the stream of commerce, a product that they knew or should have known was not safe. Merck was also negligent in the post-market safety surveillance of such drugs, and negligently failed to detect and warn about the increased frequency of adverse events associated with such drug. Merck negligently failed to adequately warn Plaintiffs, Decedents, and/or their physicians about the adverse events associated with Vioxx. Further, Merck failed to warn the Plaintiffs, Decedents, and/or their physicians or the public that Vioxx was not safe. Merck assumed a duty to warn the Plaintiffs and Decedents directly, because Merck voluntarily contacted entities other than Plaintiffs and Decedents' physicians when marketing and aggressively promoting this drug. Further, Merck failed to first determine that the product was safe for all applicable foreseeable uses.

MISREPRESENTATION AND FRAUD

6.1 Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein and additionally or in the alternative, if same be necessary, alleges as follows:

6.2 Merck, through advertising, labeling (as found in the PDR or otherwise provided to prescribing and/or treating physicians), and other communications, including

those outlined in the Background Facts of this pleading, made misrepresentations to physicians and the public, including the prescribing physicians for Plaintiffs or Decedents, about the safety and efficacy of Vioxx for controlling pain caused by inflammation. These physicians and their patients justifiably relied on Merck's misrepresentations and were harmed as a result. Plaintiffs are entitled to recover damages since such damages were produced by or the result of Merck's misrepresentations. See Restatement (Second) of Torts '402B.

6.3 Further, Merck, through advertising, labeling, promotion, and other communications intentionally made misrepresentations to physicians and the public, including the prescribing physicians for Plaintiffs and/or Decedents, about the safety and efficacy of Vioxx for controlling pain. From its inception until its withdrawal, the labeling for Vioxx and other representations of Merck were inaccurate and misleading. These misrepresentations include those found in the Background Facts of this pleading and the product labeling for Vioxx.

6.4 Merck knew, or should have known, that Vioxx was not as effective as competing anti-inflammatory pain medications, but Merck chose to disregard, downplay, and conceal that information.

6.5 Physicians and their patients, including Plaintiffs, Decedents, and/or their physicians, relied on Merck's fraudulent misrepresentations, and Plaintiffs and/or Decedents were harmed as a result. Further, because Merck's conduct was willful, reckless, intentional and maliciously fraudulent, Plaintiffs are entitled to an award of exemplary damages in order

to punish such conduct and to deter such conduct in the future.

BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY

7.1 Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein and additionally or in the alternative, if same be necessary, allege as follows:

7.2 Defendant's Vioxx was not of merchantable quality and not fit for the ordinary purposes for which such a product is used.

7.3 At the time Merck marketed, sold and distributed Vioxx for use by s, Merck impliedly warranted the product to be fit for a particular purpose and for the ordinary purpose for which such product was to be used, i.e., the treatment of arthritis pain and acute pain. Merck had reason to know of the particular purpose for which Vioxx was required. Plaintiff and/or Plaintiff's physicians reasonably relied upon the skill and judgment of Defendant to select or furnish a suitable product that was of merchantable quality and safe for its intended use.

7.4 As a direct and proximate result of Defendant's defective and unreasonably dangerous Vioxx and the breach of these implied warranty of merchantability, Plaintiffs were injured and will continue to suffer injury, harm, and economic loss, as alleged herein.

BREACH OF THE IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

8.1 Plaintiffs incorporate by reference each proceeding and succeeding paragraph as though set forth fully at length herein and additionally or in the alternative, if same be necessary, allege as follows:

8.2 Defendant's Vioxx was not fit for its particular purpose of safely treating arthritis pain or acute pain.

8.3 Defendant Merck actually and/or constructively knew of the purposes to which its Vioxx was to be used.

8.4 Plaintiffs and/or Decedent relied upon Defendant to furnish Vioxx in a condition suitable for its particular purpose.

8.5 As a direct and proximate result of Defendant's defective and unreasonably dangerous Vioxx and its breach of implied warranty of fitness for a particular purpose, Plaintiffs were harmed as alleged herein.

BREACH OF EXPRESS WARRANTY

9.1 Plaintiffs incorporate by reference each proceeding and succeeding paragraph as though set forth fully at length herein and additionally or in the alternative, if same be necessary, allege as follows:

9.2 Merck expressly warranted to Plaintiffs, Decedents, and/or their physicians that Vioxx was safe and effective when Merck knew the product had never been proven as safe and effective, when Merck knew that substantial questions existed with respect to the safety and efficacy of this product, and when, in fact, the product was not safe or effective for all foreseeable uses.

GROSS NEGLIGENCE/MALICE

10.1 The acts and omissions of Merck, whether taken singularly or in combination with others, constitute gross negligence/malice that proximately caused the injuries alleged

herein. Merck's conduct was more than momentary thoughtlessness or mere inadvertence, but it amounted to such an entire want of care so as to constitute gross negligence and/or malice. Plaintiffs seeks exemplary damages in an amount that would punish Merck for its unconscionable conduct and which would deter other similarly situated drug manufacturers, distributors, and promoters from engaging in such misconduct in the future.

AGENCY

11.1 Whenever in this petition it is alleged that Merck did any act or thing, it is meant that it performed or participated in such act or thing, or that such act was performed by the officers, agents, employees or representatives (including, but not limited to "detail men" and salespersons) of Merck. In each instance, the officers, agents, employees or representatives of Merck were then authorized to and did in fact act and/or make representations on behalf of Merck, or otherwise acted under the guidance and direction of Merck, and Merck ratified all such acts.

ALLEGATIONS AND CAUSES OF ACTION IN THE ALTERNATIVE

12.1 All factual allegations and/or causes of action alleged by Plaintiffs herein are made in the alternative.

CAUSATION

13.1 Each of the aforementioned acts, omissions, negligence, gross negligence, and/or causes of action was a proximate and/or a producing cause of the injuries to Plaintiffs and/or Decedents.

TOLLING OF LIMITATIONS

14.1 Further, Merck through advertising, labeling, promotion, and other communications intentionally made misrepresentations to physicians and the public, including Plaintiffs, Decedents, and/or Plaintiffs physicians and fraudulently concealed information about the safety and efficacy of Vioxx. Because Merck failed to adequately warn Plaintiffs, Decedents, and/or their physicians or the public that Vioxx was not safe and Plaintiffs, Decedents, and/or their physicians relied on this information to Plaintiffs or Decedents' harm, Merck is estopped from relying on the defense of limitations until Plaintiffs or Decedents knew and understood or through reasonable care and diligence, should have known of the existence of and understood the nature of the claims against Defendants. None of Plaintiffs or Decedents knew and understood or through reasonable care and diligence, should have known of the existence of and understood the nature of the claims against Merck until within one year of the filing of this complaint.

14.2 Additionally or in the alternative, if same be necessary, because each Plaintiff and/or Decedent belongs to a class that is the subject of a pending class action, the applicable statute of limitations is tolled as to each Plaintiff and/or Decedent. Each Plaintiff is part of a pending class action, including the action filed as *In re Vioxx Products Liability Litigation*, in the United States District Court Eastern District of Louisiana, MDL Docket No. 1657, Section L on August 2, 2005

AGENCY

15.1 Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

15.2 Whenever in this petition it is alleged that Merck did any act or thing, it is meant that it performed or participated in such act or thing or that such act was performed by the officers, agents, employees, or representatives (including, but not limited to, "detail men" and salespersons) of Merck. In each instance, the officers, agents, employees, or representatives of Merck were then authorized to and did in fact act and/or make representations on behalf of Merck, or otherwise acted under the guidance and direction of Merck, and Merck ratified all such acts.

DAMAGES

16.1 As a result of the foregoing, each Plaintiff sustained and seeks recovery for significant injuries and damages, including the following:

16.2 For each individual Plaintiff, past and future:

A. reasonable and necessary medical expenses for the treatment of Plaintiff's injuries and other expenses of care for Plaintiff;

B. compensation for physical pain and suffering, disfigurement, physical impairment, loss of enjoyment of life, and mental anguish; and

C. lost wages and earning capacity;

16.3 For each Plaintiff asserting claims individually and as representative of a Decedent, Estate, or heirs:

A. medical expenses and costs of care incurred by the decedent prior to death;

B. funeral, burial, and related expenses;

C. compensation for Decedent's pain and suffering;

D. all past and future loss of wages, salaries, income, and employment benefits suffered by Decedent or Decedent's estate and/or such monetary benefits or financial support which Plaintiff and/or all heirs would have received had Decedent survived;

E. past and future compensation for loss of companionship, support, consortium, and other compensatory damages to which Plaintiff and/or all heirs are entitled; and

F. all wrongful death and/or survivor or other damages to which Plaintiff, Decedent's Estate and/or heirs are entitled.

16.4 For all individual Plaintiffs and Plaintiffs asserting claims individually and in a representative capacity:

A. reasonable attorney's fees, to the extent allowed, and expenses;

B. exemplary and/or punitive damages, as allowed by law;

C. prejudgment and post-judgment interest as allowed by law,

D. costs of court; and

E. all other relief, both in law and in equity, to which Plaintiffs may be entitled.

JURY DEMAND

17.1 Plaintiffs respectfully demand a trial by jury.

PRAYER

WHEREFORE, Plaintiffs request that Defendant be cited to appear and answer herein, and that upon final trial, Plaintiffs have:

1. judgment in each Plaintiffs and/or Decedents' favor and against the Defendant, Merck;

2. all past and future compensatory damages as described above, including but not limited to all damages to which each Plaintiff is

entitled as an individual or survivor/heir and in any representative capacity or on behalf of a decedent's estate or heirs;

3. exemplary and punitive damages in an amount in excess of the jurisdictional limit;

4. all elements of interest, including, but not limited to, pre-judgment and post-judgment interest in the maximum amount as allowed by law;

5. costs of court; and

6. all such further relief to which Plaintiffs may be justly entitled.

Respectfully submitted,

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ATTORNEYS FOR PLAINTIFF

Certificate of Service

On September 28, 2006, a true and complete copy of this Complaint and Notice was served on counsel for Defendant Merck as follows:

Ellen M. Gregg, Esq.
Womble, Carlyle, Sandridge & Rice, PLLC
301 N. Main Street, Suite 300
Winston Salem NC 27101

Via MDL@wcsr.com by e-mail service, in accordance with PreTrial OrderNo. 15, and by posting to the Lexis-Nexis File & Serve to Vioxx MDL 1657 in accordance with PreTrial Order No. 8.

JASON C. WEBSTER
Attorney for Plaintiff